

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIOVAIL LABORATORIES INTERNATIONAL SRL)	
a corporation of Barbados,)	
)	
Plaintiff,)	C.A. Nos. 05-586 (GMS)
)	05-730 (GMS)
v.)	06-620 (GMS)
)	(CONSOLIDATED)
ANDRX PHARMACEUTICALS, LLC and)	
ANDRX CORPORATION,)	
)	
Defendants.)	
<hr/>		

**BIOVAIL'S ANSWERING BRIEF IN OPPOSITION TO ANDRX'S MOTION
TO STRIKE THE SUPPLEMENT TO THE EXPERT
REPORT OF GERALD S. BRENNER, Ph.D.**

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NATURE AND STAGE OF THE PROCEEDING

Plaintiff Biovail Laboratories International SRL (“Biovail”) filed this patent infringement suit under the Hatch-Waxman Act against Andrx Pharmaceuticals, LLC and Andrx Corporation (“Andrx”), after Andrx filed an Abbreviated New Drug Application (“ANDA”) with the Food and Drug Administration (“FDA”) seeking approval to market generic versions of Biovail’s highly successful blood pressure medication Cardizem® LA. In consolidated suits, Biovail has sued Andrx for infringement of U.S. Patent Nos. 5,529,791 (the “791 patent”) and 7,108,866 (the “866 patent”).

Andrx has filed a motion to strike the summary judgment declaration¹ and supplement to the expert report of Biovail’s expert Gerald S. Brenner, Ph.D. (D.I. 153). This is Biovail’s opposition to that motion.

SUMMARY OF ARGUMENT

Andrx’s motion does not tell an accurate story about the events in this case. At the outset, Andrx fails to tell the Court that it bears the burden of proving the affirmative defense of collateral estoppel. Andrx also omits that it never submitted any expert reports in support of such a defense. Because Biovail does not bear the burden of proof on collateral estoppel, Biovail did not submit an initial expert report specifically addressing this issue. And because Andrx did not submit any expert report to support a

¹ Andrx’s request to strike the summary judgment declaration is moot because the parties’ cross-motions for summary judgment, including Dr. Brenner’s declaration in support of Biovail’s motion, have been withdrawn. (D.I. 130). Accordingly, Biovail understands the present challenge to be to Dr. Brenner’s expert report supplement, which incorporates the content of his summary judgment declaration.

collateral estoppel defense, Biovail had no reason to submit an expert report to rebut an issue not raised in Andrx's expert reports.

Less than three months after expert reports were served, Andrx filed a motion for summary judgment based on the doctrine of collateral estoppel. As support for the motion, Andrx relied on a declaration of its scientist-employee, Dr. Cheng. Biovail immediately notified Andrx that it would respond with an expert declaration by Dr. Brenner, whom Biovail had previously identified and who also had previously submitted expert reports. Biovail then opposed Andrx's motion for summary judgment and submitted a declaration by Dr. Brenner in support of its opposition. When the parties voluntarily withdrew their motions and the corresponding declarations, Biovail promptly incorporated those opinions into a formal expert report so there was no risk of misunderstanding as to whether Dr. Brenner might offer those opinions at trial should they be necessary. There was no bad faith scheme to flout this Court's scheduling orders.

Nor has Andrx shown substantial prejudice if Dr. Brenner is permitted to offer the opinions in his expert report supplement. Andrx has known about Dr. Brenner's opinions for three months now. Months ago, Andrx prepared to consult with its own expert, Professor Bodmeier, regarding Dr. Brenner's opinions. And Dr. Brenner has not even been deposed yet. His deposition presumably will take place during the time set for expert depositions in June and July, 2007.

Andrx essentially argues for automatic exclusion because Dr. Brenner's supplement occurred after the period for reports in the Scheduling Order. The Third Circuit, however, has made clear that automatic exclusion is inappropriate. Exclusion is

reserved only for egregious situations involving bad faith and substantial prejudice.

Nothing like that has occurred here.

For the reasons set forth below, Biovail respectfully requests that Andrx's motion to strike be denied.

STATEMENT OF FACTS

A. Andrx's Failure to Submit an Expert Report on Its Affirmative Defense of Collateral Estoppel

On July 7, 2006, pursuant to the Court's June 23, 2006 Scheduling Order (D.I. 85), the parties served initial expert reports addressing issues on which they bore the burden of proof. On that date, Biovail submitted two expert reports on infringement showing that the claims of the '791 patent cover the diltiazem hydrochloride *tablets* identified in Andrx's ANDA No. 77-686, which are the products accused of infringement in this action. (Exh. 1; Exh. 2).² The first expert report, by Dr. Martyn Davies, contained results of actual testing of the accused infringing tablets. (Exh. 1). The second expert report by Dr. Gerald Brenner, explained how the accused tablets read on the '791 patent claims. (Exh. 2).

Andrx argues that Biovail's initial expert reports on infringement could have, or should have, included a comparison of the accused *tablet* products to *capsule* products, covered by a different ANDA (No. 75-401), that were at issue in a prior litigation between Biovail and Andrx. (D.I. 154 at 5-6). But such a comparison would not have been proper or relevant to Biovail's infringement analysis. As the Federal

² "Exh. __" refers to exhibits attached to the accompanying Declaration of Preston K. Ratliff II, Esq.

Circuit has repeatedly emphasized, “it is error for a court to compare in its infringement analysis the accused product or process with the patentee’s commercial embodiment or other version of the product or process; *the only proper comparison is with the claims of the patent.*” *Zenith Labs. Inc. v. Bristol-Myers Squibb Co.*, 19 F.3d 1418, 1423 (Fed. Cir. 1994) (emphasis added). Biovail’s initial expert reports on infringement thus contained precisely the analysis the Federal Circuit has said is required to satisfy a patentee’s burden of proof.

The only reason to compare the accused tablet products in this case to the capsule products of the prior litigation would be for collateral estoppel purposes. But collateral estoppel is an affirmative defense to a claim of infringement that must be proved by the accused infringer, here Andrx. *Novartis Pharms. Corp. v. Abbott Labs.*, 375 F.3d 1328, 1333 (Fed. Cir. 2004) (“The party seeking to invoke collateral estoppel bears the burden....”) (citing *Dici v. Pennsylvania*, 91 F.3d 542, 548 (3d Cir. 1996)). Thus, Andrx would have been the party obligated to submit an expert report by July 7, 2007 addressing collateral estoppel, had it wished to do so. In other words, Andrx would have been expected to submit an initial expert report comparing the accused *tablet* products covered by the ANDA at issue in this case, to the *capsule* products covered by the different ANDA from the prior case, in an effort to try to establish that the two products are in fact identical and raise identical issues to those actually litigated in the prior suit. *E.g., Del Mar Avionics, Inc. v. Quinton Instrument Co.*, 836 F.2d 1320, 1324 (Fed. Cir. 1987) (“A device not previously before the court and shown to differ from those structures previously litigated, requires determination on its own facts.”).

Andrx submitted two expert reports directed to its allegations that the '791 patent is invalid and unenforceable, other defenses on which Andrx bears the burden of proof, but never submitted any expert report on the issue of collateral estoppel showing identity of the accused tablet products and resulting infringement issues in the present litigation with the capsule products previously litigated.

On September 11, 2006, the parties submitted rebuttal expert reports. In its rebuttal reports on non-infringement, Andrx again did not address the issue of collateral estoppel. And, because Andrx never submitted an initial expert report on collateral estoppel, Biovail did not submit a rebuttal report directed to that issue.

On October 18, 2006, more than a month after the deadline for rebuttal expert reports, Andrx submitted a supplemental expert report of Professor Niemczyk. (Exh. 3, Certificate of Service dated October 18, 2006). Andrx did not seek leave of Court for this late submission.³ This report did not address the issue of collateral estoppel and Andrx again did not seek to submit any expert report on the issue.

B. Andrx Files a Summary Judgment Motion Based On Collateral Estoppel Relying on Its Employee-Expert Dr. Cheng

In November 2006, Andrx filed a motion for summary judgment, styled as seeking judgment of non-infringement, but was based on its assertion of collateral estoppel. (D.I. 108). Andrx's motion was filed just before the year-end holidays, well

³ Prior to serving its late expert report, Andrx stated that Professor Niemczyk could not open certain electronic files Biovail produced prior to his vacation. (Exh. 4, S. Maddox October 9, 2006 letter to D. Conde). Biovail had provided the instructions how to open those files at least as of August 25, 2006, prior to the September 11, 2006 date for rebuttal reports, and almost two months before Andrx served Professor Niemczyk's supplemental report. (Exh. 5, P. Ratliff August 25, 2006 letter to D. Carston). In any event, Andrx considered this reason sufficient for a late submission without leave of Court.

before the deadline for filing dispositive motions. In support of its motion, Andrx filed a declaration of Andrx employee Dr. Xiu-Xiu Cheng, purporting to compare the tablet products of ANDA No. 77-686 accused of infringement in the present case, with the capsule products of ANDA No. 75-401 accused of infringement in the prior litigation. Andrx's recognized in its motion that it was not "a typical summary judgment motion in a patent case." (D.I. 109 at 1). Andrx argued that a prior litigation had resolved the "same issue" of whether the same Andrx products, once ingested, infringed the patent in suit. (*Id.* at 1, 5).

Although Andrx never identified Dr. Cheng as an expert, it sought to bolster Dr. Cheng's declaration by citing her ten years of experience at Andrx, her "Ph.D in chemical engineering from West Virginia University" and her "post doctorate research at West Virginia School of Pharmacy." (D.I. 111, Exh. 2 at ¶¶1-2). Dr. Cheng's declaration described her views with regard to technical manufacturing documents and the alleged identity of Andrx's products in this case to those in the prior litigation. (*Id.* at Exh. 2 at ¶¶7-14). Dr. Cheng further opined that scaling up the manufacturing process had no effect on the composition or properties of the beads. (*Id.* at Exh. 2 at ¶12).

Biovail immediately advised Andrx that it needed time for its expert to consider Andrx's collateral estoppel assertions. (Exh. 6, J. Blumenfeld Nov. 30, 2006 email to R. Horwitz). Andrx refused Biovail's request, forcing Biovail to file a motion for an extension. In its opposition to Biovail's extension motion, Andrx acknowledged that Biovail intended to respond with an expert opinion from Dr. Brenner. (D.I. 113 at 1).

C. Dr. Brenner Submits A Declaration Rebutting Dr. Cheng's Declaration and Andrx Readies Its Own Expert, Professor Bodmeier

On January 19, 2007, Biovail filed its opposition to Andrx's motion for summary judgment and also filed a cross-motion for summary judgment of no collateral estoppel. (D.I. 125-128). In support thereof, Biovail submitted a declaration of Dr. Brenner to rebut Dr. Cheng's and Andrx's assertions that the capsule products in the prior litigation are identical to the tablets in the present litigation and raised identical infringement issues. (D.I. 126 at 11-14).

In response, Andrx's counsel notified Biovail's counsel on January 29, 2007 that Andrx "wish[ed] to provide a declaration from Bodmeier in response to Biovail's new Brenner testimony -- for the Court's consideration in the event that the Court decides to consider the new Brenner testimony." (Exh. 7, S. Maddox Jan. 29, 2007 email to P. Ratliff).

Before briefing on the summary judgment motions was complete, the parties withdrew their respective summary judgment motions following a telephone conference with the Court. (D.I. 130). Promptly following that conference, on March 7, 2007, Biovail advised Andrx that it was formally supplementing Dr. Brenner's expert report to include the information from the declaration Dr. Brenner had submitted in connection with the summary judgment motions. (Exh. 8, P. Ratliff March 7, 2007 letter to S. Maddox).

Andrx waited over a month later to file this motion -- some three months after Biovail disclosed Dr. Brenner's supplemental opinions in the summary judgment declaration.

No expert depositions have yet been taken in this case. Accordingly, Andrx will have the opportunity to depose Dr. Brenner regarding the opinions contained in his supplemental report.

ARGUMENT

A. Applicable Law

Andrx's brief does not address the controlling decision of the Third Circuit on the issue of motions to exclude expert testimony, *In re Paoli Railroad Yard PCB Litig.*, 35 F.3d 717, 791-92 (3d Cir. 1994). Recognizing that "[t]he exclusion of critical evidence is an 'extreme' sanction," the *Paoli* court held that a court should not order expert opinions excluded "absent a showing of willful deception or 'flagrant disregard' of a court order by the proponent of the evidence." *Id.* at 792.

When determining whether expert testimony should be excluded under Rule 37, the factors a district court should consider are: (1) the prejudice or surprise of the party against whom the excluded witness would have testified, (2) the ability of that party to cure the prejudice, (3) the extent to which non-exclusion would disrupt the trial, (4) bad faith or willfulness in failing to comply with the Court's deadlines. *Id.* at 791.

The *Paoli* court reversed the district court's exclusion order. It found that defendants suffered minimal prejudice where they knew of the existence of the witness during the expert discovery period and knew the substance of his expected testimony four months before the trial date. *Id.* at 792. Further, the Third Circuit refused to infer bad faith and willfulness based on a failure to meet a scheduling deadline. *Id.* at 793.

B. There Was No Bad Faith Disregard Of This Court's Scheduling Order

During the '791 patent expert report period, Biovail submitted an initial expert report fully detailing the opinions of its experts on the issues of infringement. Andrx submitted initial expert reports on the issue of validity and unenforceability. Each party then served rebuttal expert reports responding to the issues raised by the initial expert reports. Andrx did not submit any expert report on its affirmative defense of collateral estoppel. Shortly thereafter, Andrx filed its motion for summary judgment of no infringement based on an affirmative defense of collateral estoppel, relying on the declaration of an employee-scientist Dr. Cheng. Biovail submitted a declaration from Dr. Brenner in support of its opposition and then promptly supplemented its expert reports to incorporate these opinions. Biovail's actions were reasonable under the circumstances and do not demonstrate bad faith.

Andrx's venomous assertion that Biovail "deliberately violated the scheduling order in a post-hoc, bad faith attempt to shore up its insufficient expert proofs" (D.I. 154 at 4), is wrong. As discussed above, Biovail did not have the burden of proof with respect to collateral estoppel. Biovail's initial expert reports set forth what, in good faith, was sufficient to support its claim of infringement. Biovail later supplemented Dr. Brenner's expert report to address a different issue -- collateral estoppel -- raised in Andrx's motion for summary judgment and Dr. Cheng's declaration.

Andrx continues with its attacks by asserting that "Biovail's lack of candor did not stop there." (D.I. 154 at 5). But there was no lack of candor. Biovail immediately advised Andrx that it intended to have Dr. Brenner submit a declaration on the collateral estoppel issue. Andrx even prepared itself to submit a responsive

declaration from its expert, Professor Bodmeier. Biovail relied on the Brenner opinions in opposition to Andrx's motion and formally added them to a supplemental expert report to avoid any confusion or misunderstanding. Notably, Andrx itself submitted a supplemental expert report without leave after the deadline set by the Court's scheduling order, yet it attacks Biovail for purportedly acting in bad faith.

The cases on which Andrx relies involved very different facts. For example, in *AstraZeneca AB v. Mutual Pharm. Co. Inc.*, 278 F. Supp. 2d 491, 501-02 (E.D. Pa. 2003), the defendants served expert reports on patent invalidity, the issue on which they bore the burden of proof, and then in the context of summary judgment on patent invalidity, submitted declarations relying on new prior art and testing from the same experts who had already opined on invalidity in both their initial and reply expert reports. *Id.* Here, Andrx had the burden to prove collateral estoppel, did not submit any expert reports addressing this issue, and then offered opinions on the issue for the first time in its motion for summary judgment. If anything, *AstraZeneca* suggests that Dr. Cheng's submission was inappropriate.

In re Safeguard Scientifics, 2004 U.S. Dist. LEXIS 23494 (E.D. Pa. Nov. 17, 2004), on which Andrx also relies, supports the conclusion that a Court should **not** strike a timely-filed Rule 56 declaration. In *Safeguard* (like *AstraZeneca*) the party that served the new summary judgment declaration had the burden of proof. The *Safeguard* court found it was both untimely and prejudicial for that party to submit an additional declaration of their expert during summary judgment to prove loss causation, when (1)

loss causation was not included in his initial expert reports, (2) loss causation was a key element in both claims at issue, and (3) he had already been deposed. *Id.*⁴

Other cases make clear that supplemental reports should be permitted where, as here, there is no undue prejudice or bad faith. *Cartier Inc. v. Four Star Jewelry Creations Inc.*, 2003 WL 22471909 (S.D.N.Y. Oct. 31, 2003) (citing *Paoli* factors in refusing to exclude a rebuttal expert report because there was no bad faith and any prejudice could be cured through deposition, even though the rebuttal report was served three weeks before trial and seven weeks after receiving the information to which it responded); *Inline Connection Corp. v. AOL Time Warner Corp.*, 2007 WL 61883 (D. Del. 2007) (denying motion to exclude expert report submitted after expert depositions where the report was submitted in response to new evidence).⁵

⁴ The remaining cases Andrx cites are distinguishable. In *Stein v. Foamex Int'l Inc.*, 2001 U.S. Dist. LEXIS 12211, *3-*4, *19 (E.D. Pa. Aug. 15, 2001), the affidavit was filed after expert depositions were taken, and concerned an issue that should have been raised in initial expert reports. In *Cuffee v. Dover Wipes Co.*, 334 F. Supp. 2d 565, 572 (D. Del. 2004), plaintiff failed to serve any expert report by the scheduling order deadline, but then served two expert reports in response to a summary judgment motion about a month before trial. Again, this would tend to suggest, if anything, that Dr. Cheng's report was improper. In *Praxair Inc. v. ATMI Inc.*, 231 F.R.D. 457, 463-64 (D. Del. 2005), expert discovery was closed, trial was less than a month away, and the court found that the need for the late-filed expert report supplement should have been evident months before. Finally, in *Union Carbide Chems. & Plastics Tech. Corp. v. Shell Oil Co.*, 270 F. Supp. 2d 525, 523-24 (D.N.J. 2003), the case was on remand when defendants submitted eight new expert reports, including four from new experts, as well as additional testing data -- all of which was excluded because defendants had an adequate opportunity to address the issues during the first trial.

⁵ The supplement to Dr. Brenner's report also was proper under Fed. R. Civ. P. 26(e)(1), which requires a party to supplement an expert report if the party learns that "in some material respect the information disclosed is incomplete . . . and if the additional or corrective information has not otherwise been made known to the other parties." After Andrx served the declaration of its scientist Dr. Cheng, Biovail determined that it required a declaration by its expert to respond. When
(continued . . .)

C. Even if Dr. Brenner's Opinions Were Untimely, Which They Were Not, Andrx Has Not Demonstrated Prejudice Sufficient To Warrant Exclusion

Allowing the additional opinions of Dr. Brenner would not cause any substantial prejudice to Andrx. *Paoli*, 35 F.3d at 792. First, Andrx cannot seriously contend that it was surprised by Dr. Brenner's expert report supplement. When Andrx raised the issue of collateral estoppel on summary judgment and relied on the declaration of an employee-scientist in support thereof, Andrx knew or should have known that Biovail would respond with an expert declaration. Biovail in any event immediately disclosed that Dr. Brenner would provide a declaration in response.

Second, Andrx knew the substance of Dr. Brenner's supplemental opinion as of January 19, 2007, almost three months before it filed this motion. Also, in January 2007, Andrx planned to consult with its own expert, Professor Bodmeier, in response. (Exh. 7, S. Maddox January 29, 2007 email to P. Ratliff). Dr. Brenner has not yet been deposed. Andrx has had months to consider Dr. Brenner's opinions and can take Dr. Brenner's deposition in the coming months. *See Inline Connection*, 2007 WL 61883, at *5 ("Prudence being the better part of valor, the court is confident that Inline and its expert have been digesting the material contained in the Supplemental Report and preparing a response thereto since its receipt rather than presuming the court would automatically exclude testimony related thereto.")

(. . . continued)

the summary judgment motions were withdrawn, it was proper for Biovail to promptly serve Dr. Brenner's expert report supplement to meet its obligations under Fed. R. Civ. P. 26(e)(1).

For all these reasons, Andrx has failed to prove that Dr. Brenner's expert report supplement will disrupt the orderly and efficient trial of the case. In light of the minimal prejudice to Andrx, exclusion should not be ordered. *Paoli*, 35 F.3d at 792 ("we have reversed an exclusion where, as is the case here, there was only a slight deviation from pre-trial notice requirements, and admitting the witness was likely to cause only slight prejudice to the defendants, who were already aware of the basic substance of the witness' testimony").

On the other hand, Biovail would suffer far greater prejudice if Dr. Brenner's expert report supplement were excluded. Andrx's tactic in moving for summary judgment shows that Andrx may seek to argue collateral estoppel at trial by relying on testimony of an employee-scientist notwithstanding that it submitted no expert report on the issue. Biovail has given Andrx full notice of Dr. Brenner's expected responsive testimony. An order excluding Dr. Brenner from providing the supplemental opinions disclosed months ago would reward Andrx for failing to submit an expert report on the issue and potentially leave undisclosed opinions of its employee-scientist unrebutted.⁶ Such a result would be contrary to the policy behind Rule 26, which "exists to avoid expert disclosure that is 'sketchy and vague,' so that litigants can be prepared for trial," *Dyson Tech. Ltd. v. Maytag Corp.*, No. 05-434 (GMS), 2007 WL 656252, *3 (D. Del. March 6, 2007), a policy met by the disclosure of Dr. Brenner's opinions in his expert reports.

⁶ Biovail reserves the right to seek exclusion of any improperly-disclosed opinions Andrx attempts to submit at trial comparing the products in this case with the products in the prior case.

CONCLUSION

For the foregoing reasons, Biovail respectfully requests that the Court deny Andrx's motion to strike Dr. Brenner's expert report supplement.

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April 25, 2007

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CERTIFICATE OF SERVICE

I, the undersigned, hereby certify that on April 25, 2007, I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing(s) to the following:

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